

WHAT IS CLAIMED:

1                    1.        A method for increasing likelihood of effectiveness of an ErbB antagonist  
 2 cancer treatment, which method comprises administering a cancer treating dose of the ErbB  
 3 antagonist to a subject, wherein an *erbB* gene in tumor cells in a tissue sample from the subject has  
 4 been found to be amplified.

1                    2.        The method according to claim 1, wherein the ErbB is a HER2 protein.

1                    3.        The method according to claim 2, wherein the cancer is breast cancer.

1                    4.        The method according to claim 3, wherein the subject has been found to have  
 2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1                    5.        The method according to claim 1, wherein the ErbB antagonist is an anti-ErbB  
 2 antibody.

1                    6.        The method according to claim 5, wherein the ErbB is HER2, and the  
 2 antibody is recombinant human monoclonal antibody (rhuMAb) 4D5.

1                    7.        The method according to claim 1 wherein the *erbB* gene amplification is  
 2 detected by detecting fluorescence of a fluorescent-labeled nucleic acid probe hybridized to the gene.

1                   8.       The method according to claim 7, wherein the *erbB* gene is a *her2* gene..

1                   9.       The method according to claim 1, which further comprises administering a  
2 cancer treating dose of a chemotherapeutic drug.

1                   10.     The method according to claim 9, wherein the ErbB is HER2 and the  
2 chemotherapeutic drug is a taxoid.

1                   11.     The method according to claim 1 wherein the likelihood of effectiveness  
2 increases by about 30%.

1                   12.     A method for increasing likelihood of effectiveness of an anti-HER2 antibody  
2 to treat cancer, which method comprises administering a cancer treating dose of the anti-HER2  
3 antibody to the subject, wherein a *her2* gene in tumor cells in a tissue sample from the subject have  
4 been found to be amplified.

1                   13.     The method according to claim 12, wherein the subject has been found to have  
2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1                   14.     The method according to claim 12, which further comprises administering a  
2 cancer treating dose of a taxoid.

1           15.    A pharmaceutical package comprising:  
2           (a)    a container comprising an ErbB antagonist for treating a cancer; and  
3           (b)    instructions to administer the ErbB antagonist to a subject if an *erbB* gene in  
4 tumor cells in a tissue sample from the subject is amplified.

1           16.    The package of claim 15, wherein the ErbB antagonist is an antibody.

1           17.    The package of claim 16, wherein the antibody is an anti-HER2 antibody.

1           18.    The package of claim 17, wherein the anti-HER2 antibody is rhuMAb 4D5  
2 (Herceptin®).

1           19.    The package of claim 15, wherein the instructions further comprise directions  
2 to administer a chemotherapeutic drug in combination with the ErbB antagonist.

1           20.    The package of claim 19, wherein the chemotherapeutic drug is a taxoid.

1           21.    A method for identifying a patient disposed to respond favorably to an ErbB  
2 antagonist for treating cancer, which method comprises detecting *erbB* gene amplification in tumor  
3 cells in a tissue sample from the patient.

2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1            23.    The method according to claim 21, wherein the *erbB* is *her2*.

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